

AWARD NUMBER: W81XWH-14-2-0007

TITLE: Early Intervention to Reduce Alcohol Misuse and Abuse in the Ohio Army National Guard

PRINCIPAL INVESTIGATOR: Joseph R. Calabrese, MD

CONTRACTING ORGANIZATION: Case Western Reserve University  
Cleveland, OH 44106

REPORT DATE: September 2015

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

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6. AUTHOR(S) Joseph R. Calabrese, MD; Frederic Blow, MD  E-Mail: joseph.calabrese@uhhospitals.org				5d. PROJECT NUMBER	
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14. ABSTRACT The proposed project is a fully-powered randomized controlled trial of a Web-based + texting alcohol brief intervention (WT-BI) versus an Enhanced Usual Care (EUC) condition for National Guard members in the State of Ohio who meet criteria for at-risk drinking in the previous 3 months. After tailoring the content of the WT-BI intervention for NG soldiers, the proposed study will screen ~ 3,100 individuals over the three year enrollment period as part of the larger ongoing longitudinal assessment of ONG members in the OHARNG MHI, to identify 750 participants with at-risk drinking. These ONG members will be randomized to either the WT-BI (n=375) or the EUC condition (n=375) and followed for one year. Enrollment has not yet begun, therefore there are no results to report at this time.					
15. SUBJECT TERMS Ohio National Guard, Mental Health, Alcohol Use Disorders, Risky alcohol use, SBIRT (Screening, Brief Intervention, Referral to Treatment) model, Risky					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT  UU	18. NUMBER OF PAGES  31	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT  U	b. ABSTRACT  U	c. THIS PAGE  U			19b. TELEPHONE NUMBER (include area code)

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1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

This project is a fully-powered randomized controlled trial of a mobile phone app - and text-based alcohol brief intervention (MT-BI) versus an Enhanced Usual Care (EUC) condition for National Guard members in the State of Ohio who meet criteria for unhealthy drinking in the previous 3 months. After tailoring the content of the MT- BI intervention for National Guard soldiers, the proposed study will screen ~ 3,100 different individuals over the three year enrollment period as part of the larger yearly ongoing longitudinal assessment of ONG members enrolled in the Ohio Army National Guard Mental Health Initiative (OHARNG MHI), to identify 750 participants with unhealthy drinking. These Guard members will then be randomized to either the MT-BI (n=375) or the EUC condition (n=375) and followed for one year post-enrollment.

The specific aims are to compare MT-BI and EUC in:

1. Reducing the frequency and intensity of at-risk drinking at 3 -,6- and 12-months;
2. Decreasing binge drinking at 3-, 6- and 12 months.

The secondary aims are to:

1. Compare the MT-BI and EUC conditions in reducing the frequency of illicit drug use and depressive symptoms at 3-, 6- and 12-months;
2. Examine if deployment status moderates the effect of intervention assignment (MT-BI or EUC) on post-intervention drinking, depressed feelings, and other substance use.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Alcohol screening, brief intervention, drinking, military, eHealth, mHealth, social support

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction.

**What were the major goals of the project?**

**Task #1: Customize mobile phone app – and text-based alcohol brief intervention for National Guard (NG) population – 25%**

Subtask 1

Facilitate focus groups, consisting of Ohio NG leadership and soldiers to develop, refine, and tailor the screening questionnaires, assessments, and risk management procedures.

Subtask 2

Create mobile phone app – and text-based alcohol brief intervention program and a project management tracking system in the first 9 months of Year 1.

**Task #2: Data Collection – 10% completed**

Subtask 1

Hire (as necessary) and train all study personnel in Year 1, with ongoing trainings held each year as needed.

#### Subtask 2

Starting in the 4<sup>th</sup> quarter of Year 1 through Year 4, enrollment of up to 750 participants (~250 participants/year over 3 years) utilizing the Ohio Army National Guard Mental Health Initiative platform for recruitment

#### Subtask 3

Participant follow-up at 3, 6, and 12 months through Year 5 (N=750)

### **Task #3: Data Dissemination – 0% completed**

#### Subtask 1

Starting in Year 2, performance of descriptive analysis of the data including, but not limited to hazardous alcohol use and deployments, and hazardous alcohol use with co-morbid illnesses, i.e. PTSD, depression.

#### Subtask 2

Upon completion of data collection, at least 1 submission to a peer-reviewed journal will be derived from the study data

#### Subtask 3

Starting in Year 2, presentations each year of the most recent alcohol data, i.e. at advisory board meetings, poster/symposium presentations at scientific conferences, and presentations for the Ohio NG, as requested.

### **Task #4: Oversight Meetings – 9% completed**

#### Subtask 1

*External Scientific Advisory Board*, providing critical feedback on the scientific merit of the project, will be held once annually, Years 1-5.

#### Subtask 2

*Administrative Advisory Board*, providing guidance on non-scientific issues, will be held once annually, Years 1-5.

#### Subtask 3

*Sponsor Scientific Meeting* (as requested) consisting of programmatic and scientific leaders to provide a scientific and fiscal update.

#### Subtask 4

*Data Safety Monitoring Board*, provide information as needed to the quarterly DSMB meetings, held by the Coordinating Center

### **Task #5: Regulatory & Reporting – 5% completed**

#### Subtask 1

Initial Submission in Year 1, Continuing Reviews in Years 2-5, and addendum submissions as needed, to applicable local IRBs of record

#### Subtask 2

Obtain Certificate of Confidentiality from DHHS in Year 1

#### Subtask 3

Initial Submission in Year 1, Continuing Review in Years 2-5, and applicable submissions to the DoD Office of Research Protections

#### Subtask 4

Quarterly financial reporting to USAMRAA, as required, in Years 1-5

#### Subtask 5

Annual progress report to USAMRMC in Years 1-4, with a Final Report at the end of Year 5.

#### Subtask 6

Progress reports to sponsoring agency (as requested)

#### **What was accomplished under these goals?**

The current award became effective on 01 Sep 2014. After we received funding, it was decided that we would revise the statement of work to change the intervention from a computer intervention to a Web/Smartphone-based + texting application. Dr. Fred Blow, the Scientific PI on this project, revised the statement of work to reflect this change. The revised statement of work was submitted to the USAMRAA Contract Specialist on 05 Jan 2015 and was approved on 24 Feb 2015. Revisions to the statement of work and subsequent approvals delayed the start of the project and work did not formally begin until March 2015.

The following was accomplished under these goals over the past year:

#### **Task #1: Customize mobile phone app – and text-based alcohol brief intervention for National Guard (NG) population**

Work is underway on the design and development of the smartphone app, which is being developed for both the Android and iOS platforms. The goal of the study is to develop, test and disseminate tools that will have a measurable, positive impact on the problems of hazardous use in the NG population. All of the options we are investigating could be distributed to all reserve component elements as a tool kit that they could implement with their National Guard members/reservists. They could be blended with existing resilience building efforts and training efforts in alcohol misuse. The key challenges are engagement in and adherence to the interventions offered.

Engagement and adherence have been a limiting factor in previous attempts to apply population based approaches to hazardous use of alcohol and other substances, including in military populations. An e-health approach has great potential for overcoming the challenges with building resilience in reserve components – their part time status and relative distance from brick and mortar military programs. We have been working on embedding strategies to engage and sustain engagement in our smartphone app, including principles of contingency management approaches to reward participants and social support strategies to improve engagement. We will employ focus groups to get feedback on all of the various components of the application to ensure it is relevant and helpful to those who use it.

#### **Task #2: Data Collection**

On 21 May 2015, study personnel from the sites met to review the following: overview of the telephone survey parent project; review the objectives of the alcohol intervention project; discuss plans for HRPO and IRB submissions across the sites; review study flow/measures; preview a smart phone application demonstration from the University of Michigan Center for Health Communications Research (CHCR); review smart phone applications similar to what we wish to do; brainstorm ideas for the smart phone application for this study; and discuss next steps. An outline of this meeting is below.

1. Introductions/roles on the study
  - a. Attendees
    - i. Frederic Blow, PhD, University of Michigan – Scientific PI
    - ii. Kristen L. Barry, PhD, University of Michigan – Co-Investigator
    - iii. Mark Ilgen, PhD, University of Michigan – Co-Investigator
    - iv. Amy Bohnert, PhD, University of Michigan – Co-Investigator
    - v. Linda Mobley, University of Michigan – IRB Coordinator
    - vi. Lynn Massey, University of Michigan – Project Coordinator
    - vii. Loree O’Jack, University of Michigan – Financial Specialist
    - viii. John Wryobeck, PhD, University of Toledo – Co-Investigator
    - ix. Richard McCormick, PhD – Independent Consultant
    - x. Carla Conroy, MPH, Case Western Reserve University – Research Manager
    - xi. Brittany Brownrigg, BS, Case Western Reserve University – Data Coordinator
    - xii. Nicole Moomaw, BA, Case Western Reserve University – Research Coordinator
    - xiii. Representatives of University of Michigan Center for Health Communications Research (CHCR)
2. Overview of the telephone survey parent project (design, structure, data collection)
3. Overall project overview
4. Review study flow and measures
  - a. Reviewed table of measures from original grant proposal
  - b. Reviewed study flow from original proposal
  - c. Reviewed project milestones from original proposal
    - i. We are in month 9 of the study and behind where we projected we would be at this time. The project is similar to the NIAAA study and this will help us move forward more quickly with this study
    - ii. We may need to ramp up staffing to catch up on time line
5. Discuss IRB submissions
  - a. Submit to CWRU, U of M and UT IRBs concurrently
  - b. CWRU will apply for Certificate of Confidentiality for all sites once IRB approval is obtained
  - c. We may want to video tape people testing the app once it is developed; IRB approval may be needed for this.
  - d. More needs to be done with app development and planning of study logistics before we can submit to IRBs
6. CHCR demo app
  - a. CHCR demoed other apps they have developed
  - b. App can be developed so that participants will have to enter an access to code to access the app content. This will prevent non-study participants or those in the control group from using the app.
  - c. Discussed the differences between a native app (one made specifically for an iPhone or an Android phone) vs. mobile web app (one that is made to launch on mobile web browser) as well as the pros and cons. It was decided that unless there is a strong reason to use a native app, we would develop a mobile web app due to lower turnaround time and cost

7. Review apps document
  - a. Reviewed other apps developed for those with alcohol/drug use disorders and mental illness and discussed pros and cons
  - b. App needs to be engaging, not just something people read though (i.e. not too “wordy”)
8. Brainstorming
  - a. It was suggested that we do testing in sections so that once a section is done, it is tested by a group of National Guard Members to get feedback from those similar to who may use the app while CHCR is working to develop the next module
  - b. We need to be able to show how the app is helping people and how they are using it.
    - i. There may be differences in changes based on how subjects use the app, so when analyzing data, we may want to look at who got the most benefit from the app and what features they used.
    - ii. We should integrate change talk in to the app
  - c. We need to be aware that not all people may be in the same stage of change (i.e. precontemplation, contemplation, preparation, action, maintenance) and develop an app that appeals to people no matter their stage of change.
    - i. We may want to have some sections that target those who think they don’t have a problem, focusing on ambivalence
  - d. The SBIRT (Screening, Brief Intervention, Referral to Treatment) model allows people to make of the intervention what they will, not tell them what is important.
  - e. The context for those around you may be more motivational (i.e. show how they compare to others in their group)
  - f. The question was brought up as to how we will ensure that those assigned to the intervention group actually complete the intervention. This is something we’ll have to explore and discuss further
    - i. One suggestion was to do Skype sessions with those assigned to the intervention where we actually walk them through the intervention so we know they were exposed.
  - g. Recruitment Issues
    - i. We need to engage participants and make this app something they want to use, even if they don’t believe they have an alcohol problem. One suggestion was made is to emphasize to potential subjects that this study is being done to look at patterns of use among ONG soldiers and how we can best help them, as opposed to focusing on them having a possible alcohol use disorder, which they may not be receptive to.
    - ii. If we are not meeting our enrollment goals after the first year, we may explore the need to recruit outside of the OHARNG-MHI study.
9. Plan next steps
  - a. Dr. Blow will engage with the Ohio National Guard and set up time to talk to ONG command.
  - b. Follow up meetings are scheduled with UM CHCR in mid to late June to develop micro-level plans. Ramp up activities in July due to various meetings and other scheduling conflicts in June.



We have continued discussions with the research team since the May meeting, including in person and teleconference meetings.

In addition, the research coordinator at Case Western Reserve University is working on the development of a protocol and informed consent template that will be used to submit this project to the various sites' IRBs.

Finally, the data coordinator at Case Western Reserve University has begun programing some of the assessments in to REDCap, the electronic data capture (EDC) system that will be used for the study.

### **Task #3: Data Dissemination**

There were no activities related to this task completed over the reporting period.

### **Task #4: Oversight Meetings**

On 22-24 September 2014, Dr. Blow attended the Substance Abuse IPR at Fort Detrick, where he gave an overview of this project and his National Institute on Alcohol Abuse and Alcoholism (NIAAA) funded project including the following information:

- Given the rapidly changing mobile health field with dramatic increases in the use of smartphone technologies, we plan to develop and test a mobile phone app for delivery of the intervention content, and for providing real-time feedback and support for drinking goals.
- Three different booster strategies will be examined across the studies (peer, web, phone text), thus providing DoD with data to weigh efficacy and cost in selecting from among these strategies for future implementation.
- Key Differences between NIAAA (Blow) and DoD projects (Calabrese)
  - Intervention Focus (alcohol + prescription drugs vs. alcohol only)
  - Delivery Platforms (web + peer delivered vs. smartphone)
  - Exploration of Mechanisms of Change (moderators/mediators)

A copy of the slides presented at the 2014 Substance Abuse IPR can be found in the appendices.

In addition, on 02 Mar 2015, we held the first External Scientific Advisory Board (SAB) Meeting for the project. During this meeting, Dr. Blow gave the SAB members an overview of this project and his NIAA funded project, similar to what was presented at the 2014 Substance Abuse IPR.

### **Task #5: Regulatory & Reporting**

Over the past reporting period we submitted quarterly financial and technical reports to USAMRAA as required.

Once sites have obtained approval from their respective IRBs, we will submit to the USAMRMC Office of Research Protections Human Research Protection Office for their approval.

**What opportunities for training and professional development has the project provided?**

This project has provided Nicole Moomaw, Research Assistant at Case Western Reserve University, with the opportunity to work on a large-scale, USAMRAA funded study. In addition, it has given her the opportunity to take a grant submission and, with the help of the principal investigator, the scientific principal investigator and the research project manager, turn it in to an IRB protocol to be used as a template for other sites to obtain their IRB approval.

**How were the results disseminated to communities of interest?**

Nothing to Report

**What do you plan to do during the next reporting period to accomplish the goals?****Task #1: Customize Computer Intervention for National Guard (NG) population**

We plan on finalizing the smartphone app and algorithms for delivery of the text messages/other intervention content in the coming months. We will engage in our NG Advisory Group on features and will conduct feasibility testing with NG volunteers. We expect to be in the field implementing the RCT in the coming project year.

**Task #2: Data Collection**

Over the next year, the University of Toledo plans to hire, study personnel for their site. In addition, once a protocol is finalized, all study personnel will be trained in the various components of the study and the data coordinator will finalize the EDC system and provide training on data entry, responding to queries and the quality assurance process that will be used during the study. Recruitment of subjects and randomization will commence as soon as we complete development and testing of the app and all IRB approvals. We expect to be in the field in summer 2016.

**Task #3: Data Dissemination**

Nothing to Report

**Task #4: Oversight Meetings**

Over the next year, we plan to have another External Scientific Advisory Board (SAB) meeting (tentatively scheduled for Spring 2016). In addition, we will hold an External Administrative Advisory Board Meeting (AAB) with members of the ONG leadership. Finally, Dr. Blow will attend the 2016 Substance Abuse IPR. Data Safety Monitoring Board Meetings will be held quarterly when subject recruitment commences.

**Task #5: Regulatory & Reporting**

Over the next reporting period, we will continue to submit quarterly financial and technical reports to USAMRAA as required. In addition, we will obtain IRB approval from all study sites, as well as from the USAMRMC Office of Research Protections Human Research Protection Office.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

**What was the impact on the development of the principal discipline(s) of the project?**

Nothing to report.

**What was the impact on other disciplines?**

Nothing to report.

**What was the impact on technology transfer?**

Nothing to report.

**What was the impact on society beyond science and technology?**

Nothing to report.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

**Changes in approach and reasons for change**

As noted above, after we received funding, it was decided that we would revise the statement of work to change the intervention from a computer intervention to a Web/Smartphone-based + texting application. This change was made so that, in conjunction with Dr. Blow's NIAAA funded study, a variety of intervention strategies could be explored in National Guard members in multiple states. To this end, Dr. Blow revised the statement of work to reflect this change. Given that this was a significant change, the revised statement of work was submitted to the USAMRAA Contract Specialist on 05 Jan 2015 for approval. It was subsequently approved on 24 Feb 2015.

**Actual or anticipated problems or delays and actions or plans to resolve them**

Because we decided to revise the statement of work to change the intervention platform and because this revision required USAMRAA approval, we were not able to begin work on the project until March 2015.

**Changes that had a significant impact on expenditures**

Delaying the startup of the study until March, 2015, impacted expenditures. The University of Toledo has delayed hiring staff until the training and recruitment commences.

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

**Significant changes in use or care of human subjects**

The University of Michigan has submitted and obtained IRB approval for an Umbrella Project. Umbrella projects are submitted as a way to seek initial approval for a project where human

subject activities have not yet been fully developed. Once a full protocol is available and submitted for approval to the coordinating center IRB, the University of Michigan will update this umbrella project to be a full, human subject's research protocol.

No other sites have obtained approval from their respective IRBs.

**Significant changes in use or care of vertebrate animals.**

No activities involving the use or care of vertebrate animals will be performed to complete this project.

**Significant changes in use of biohazards and/or select agents**

No activities involving the use biohazards and/or select agents will be performed to complete this project.

**6. PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**  
Nothing to Report
- **Books or other non-periodical, one-time publications.**  
Nothing to Report
- **Other publications, conference papers, and presentations.**  
Nothing to report.
- **Website(s) or other Internet site(s)**  
Nothing to Report
- **Technologies or techniques**  
Nothing to Report
- **Inventions, patent applications, and/or licenses**  
Nothing to Report
- **Other Products**  
Nothing to report.

**7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

**What individuals have worked on the project?**

Name: Joseph R. Calabrese, MD

Project Role: Principal Investigator

Researcher Identifier (e.g. ORCID ID): ERA Commons - jcalabrese

Nearest person month worked: 0.3 calendar months

Contribution to Project: Oversight of grant negotiations including submission of requested documents to the Contract Specialist; ongoing administration and oversight of all aspects of the Ohio Army National Guard Mental Health Initiative.

Name: Mary Beth Serrano, MA

Project Role: Project Manager

Researcher Identifier (e.g. ORCID ID): N/A

Nearest person month worked: 1.8 calendar months

Contribution to Project: Ms Serrano provided administrative support during this reporting period.

Name: Brittany Brownrigg

Project Role: Data Coordinator

Researcher Identifier (e.g. ORCID ID): N/A

Nearest person month worked: 1.2 calendar months

Contribution to Project: Ms. Brownrigg provided data management support researching project tracking tools and working with the UH RedCap database team.

Name: Nicole Moomaw, BA

Project Role: Research Assistant II

Researcher Identifier (e.g. ORCID ID): N/A

Nearest person month worked: 2.4 calendar months

Contribution to Project: Ms. Moomaw participated in project start-up activities and sessions and began protocol development and regulatory activities.

Name: Frederic C. Blow, PhD

Project Role: Scientific Principal Investigator

Researcher Identifier (e.g. ORCID ID): ERA Commons - fredblow

Nearest person month worked: 3.0 calendar months

Contribution to Project: Dr. Blow attended the study meeting in May and provided ongoing oversight of the initiative.

Name: Kristen Barry Haenchen, PhD

Project Role: Co-Investigator

Researcher Identifier (e.g. ORCID ID): ERA Commons - kbarry

Nearest person month worked: 1.8 calendar months

Contribution to Project: Dr. Haenchen began to develop intervention content for the mobile phone app.

Name: James A. Cranford, PhD

Project Role: Co-Investigator

Researcher Identifier (e.g. ORCID ID): ERA Commons - jcranfor

Nearest person month worked: 0.8 calendar months

Contribution to Project: Dr. Cranford worked with Dr. Haenchen on content of the intervention and on how micro-level data will be analyzed.

Name: Lynn Massey, LMSW  
Project Role: Project Manager  
Research Identifier (e.g. ORCID ID): N/A  
Nearest person month worked: 0.8 calendar months  
Contribution to Project: Ms. Massey coordinated the initial meetings to design the development of the intervention app.

Name: Mary Jannausch, MS  
Project Role: Data Manager/Analyst  
Researcher Identifier (e.g. ORCID ID): N/A  
Nearest person month worked: 5.0 calendar months  
Contribution to Project: Ms. Jannausch worked on developing data dictionaries and data analytic plans during this reporting period.

Name: Holly Derry  
Project Role: CHCR Staff  
Researcher Identifier (e.g. ORCID ID): N/A  
Nearest person month worked: 1.0 calendar months  
Contribution to Project: Ms. Derry has been writing the content for the intervention app.

Name: Ian Moore  
Project Role: CHCR Staff  
Researcher Identifier (e.g. ORCID ID): N/A  
Nearest person month worked: 1.2 calendar months  
Contribution to Project: Mr. Moore has been writing code and designing the graphics for the app.

As we have not yet started study specific trainings and/or enrolled subjects, no one from the University of Toledo has works at least one person month per year on the project during the reporting period.

**Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Nothing to report

**What other organizations were involved as partners?**

Nothing to report.

## **8. SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:** For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

Not applicable

**QUAD CHARTS:** If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

Not applicable - Quad Chart was not submitted with initial grant submission

## **9. APPENDICES**



# Early Intervention to Reduce Alcohol Misuse and Abuse in the Ohio Army National Guard

**Coordinating PI: Joseph Calabrese, MD, Case Western Reserve**  
**Scientific PI: Frederic Blow, PhD, University of Michigan**

**Award Number: W81XWH-14-2-0007**

**Total award: \$3,667,349**

**Contract Officer: Janet P Kuhns**

**Project Officer: Lance Nowell**



# **Collaborators & Acknowledgements**

**University of Michigan**

**Amy Bohnert, Ph.D.**

**Kristen Barry Haenchen, Ph.D.**

**Mark Ilgen, Ph.D.**

**University of Toledo**

**John Wryobeck, Ph.D.**

**Case Western**

**Richard McCormick, Ph.D.**

**Ohio National Guard**

**TAG MJ Deborah Ashenhurst**

**Colonel Julie Blike**

**Captain Sephan Frazier**

**Jeremy Kauffman, Psy.D**

**ATAG BJ John Harris**

# Ohio Army National Guard Mental Health Initiative—Primary Platform

**Coordinating PI:**  
**Scientific PI:**

**Joseph Calabrese, MD**  
**Sandro Galea, MD, DrPH**

**FY06 - FY11**

**House Congressional Allocation**

**Award Numbers: W81XWH-07-1-0409: 5/7/2007 – 5/6/2012**

**W81XWH-10-1-0579: 9/28/2010 – 9/27/2014**

**Total award increased: \$956,289 from \$3,499,000 to \$4,455,289  
thru Warfighter 1/1/2014 - 9/27/14**

**Remaining award: \$206,017**

**Contract Officer: Amber Shryer**

**Project Officer: Michelle Lane**



**CASE WESTERN RESERVE**  
**UNIVERSITY** EST. 1826



**Columbia University**  
**MAILMAN SCHOOL**  
**OF PUBLIC HEALTH**

## **Co-PIs & Acknowledgements**

**Columbia University**

**Scientific Principal Investigator – Sandro Galea, MD, DrPH**

**Ann Arbor VA**

**Dir., Translational Research - Israel Liberzon, MD**

**University of Toledo**

**Co-PI – Marijo Tamburrino, MD**

**Abt. SRBI, Inc**

**Telephone Survey Data Collection Firm – Mark Morgan**

**Ohio National Guard**

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## Background & Rationale

### Existing Efforts

- **1<sup>st</sup> prospective study to use pre- and peri- deployment Guard data to meet the real-time prioritized translational needs of vulnerable subgroups.**

### Uniqueness

- **Focus on how pre-, peri-, and post-deployment factors jointly predict distinct trajectories of posttraumatic psychopathology**
- **How interpersonal, intrapersonal, and contextual factors jointly predict distinct trajectories of posttraumatic psychopathology**
- **How both military and civilian experiences shape longitudinal risk for psychopathology.**
- **Examining the association between PTSD symptoms and novel genetic loci, while replicating previous findings of G x E interaction effects in FKBP5 and 5-HTTLPR (ACNP 2012 manuscript under review)**

### Value

- **Feedback from Guard leadership led to a 2013 submission of a secondary prevention study targeting hazardous alcohol use in soldiers not yet deployed (Frederic Blow – funded and ongoing).**
- **Study results led to revisions of the Ohio Guard's Suicide Prevention Annual Training Program highlighting the relationship between suicide and Axis I comorbidity (Calabrese et al 2011).**

# Value Projecting into the Future

- Identified and published new findings on key factors in the Guard, including priority problems like suicidality and its risk factors, PTSD, hazardous use of alcohol and other risk behaviors, sexual harassment and assault, and utilization of mental health resources.
- Quickly translated key findings on the high incidence of hazardous alcohol use, a gateway for other problems, into a funded pragmatic study of a unique web- and text-based brief intervention available to soldiers world-wide at little or no cost.
- Attracted and embraced requests from other DoD-funded investigators for use of the platform.
- Ongoing collaboration with Ohio Guard leadership in the identification of priority problems, e.g. revisions to the Suicide Annual Training Program, alcohol abuse, sexual assault, etc.

# Research Questions & Hypotheses

## Telephone Project

•**AIM 1:** Examine the roles of pre-, peri-, and post-deployment experiences, both military and civilian, in jointly contributing to trajectories of psychopathology over a decade of follow-up.

•**H1** - Pre-, Peri-, and post-deployment factors will jointly predict distinct trajectories of posttraumatic psychopathology.

•**H2** - Interpersonal, intrapersonal, and contextual factors will jointly predict distinct trajectories of posttraumatic psychopathology.

•**H3** - Military and civilian experiences co-equally shape longitudinal risk for psychopathology among ONG soldiers.

•**AIM 2:** To assess the polygenic drivers of the trajectories of psychopathology over long-term follow-up of a reserve population.

•**H1** - Trajectories of psychopathology over a decade of follow-up will be predicted by genetic markers at multiple loci.

•**H2** - Genetic loci will act in concert with environmental factors (e.g. traumatic events, social support, and geographic features) to shape trajectories of psychopathology.

•**AIM 3:** To examine the role of hazardous alcohol use and alcohol use disorders in the multimorbidity of PTSD, depression, TBI and other psychopathology, and their chronicity over a decade of follow-up.

•**H1** - Hazardous alcohol use and alcohol use disorders will be associated with new onset of psychiatric disorders.

•**H2** - Hazardous alcohol use and alcohol use disorders will strongly predict chronicity of comorbid psychiatric disorders.

# Research Questions & Hypotheses

## Genetics Repository

- **AIM 1:** Identify specific molecular genetic factors associated with vulnerability and resilience to deployment- and combat-related psychiatric disorders
  - **H1** – Genetic variants are associated with post-deployment PTSD and other stress-related psychiatric syndromes and symptoms in military personnel.
  - **H2** – Risk alleles interact with the severity and characteristics of deployment stress, and with pre- and post-deployment environmental factors (e.g. psychosocial factors including lifetime stress / trauma history, early life adverse events) to lead to greater PTSD risk following trauma.



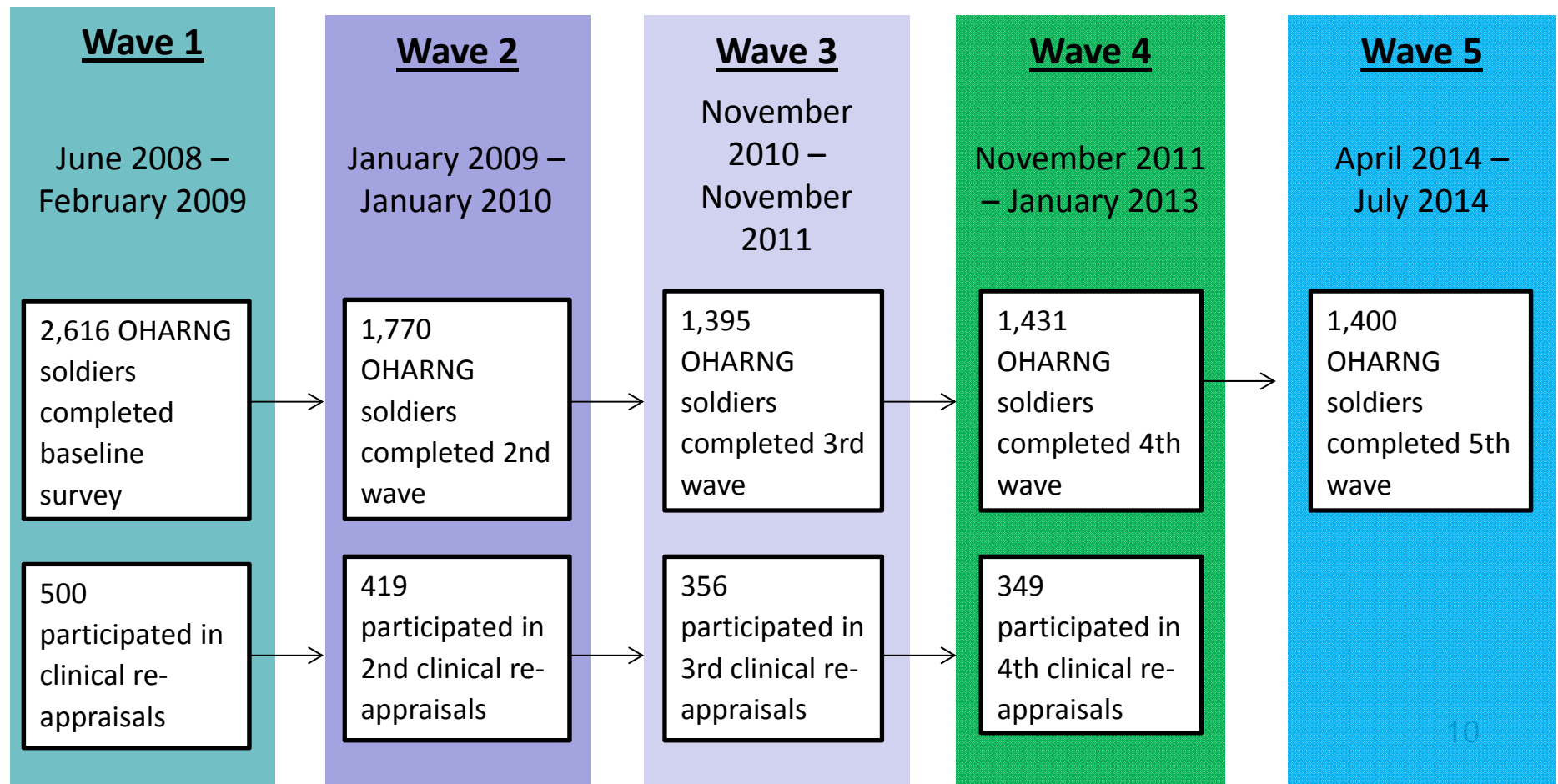
# Research Questions & Hypotheses

## Neuroimaging

- AIM 1: Demonstrate differential activation patterns in response to: emotional processing tasks, cortical thickness of activated regions, and white matter connectivity of frontal cortex and amygdala in adults with 1) a history of childhood adversity (CA) who develop PTSD, 2) CA who developed PTSD after adulthood deployment-related trauma, and 3) with both CA and adult trauma who did not develop PTSD
  - H1 – Childhood adversity shapes neurocircuits underlying emotional regulation, which can lead to PTSD development after CA or upon exposure to additional trauma in vulnerable individuals, but not in highly resilient individuals.
- AIM 2: Explore the feasibility of gene (stress-related) by environment (CA) interactions on promoting changes in brain function (amygdala and mPFC response to emotion tasks) and structure (cortical thickness and white matter connectivity) known to be associated with PTSD after child and/or adulthood traumas.
  - H2 – Childhood adversity interacts with genetic factors to produce individual differences in brain structure and function, which contribute to vulnerability/resilience to the development of PTSD upon adult trauma exposure.

# Design and Methodology – Follow-up

- Methodology utilizes state of the art follow-up procedures and a dynamic cohort to maximize ongoing participation.



# Impact of Alcohol Use

Within the OHARNG cohort, examined pre-, peri-, and post-deployment trajectories of depression and PTSD over ~4 years of follow-up. For those with alcohol abuse and dependence:

- 5% had severe chronic symptoms that worsened
- 11% had persistent mild symptoms
- 38% had mild symptoms that remitted
- 46% were entirely resistant to the development of PTSD
- **Over 4 years of follow-up, chronic alcohol misuse increased PTSD-symptom-severity 9.3%**
- **Over 4 years of follow-up, chronic alcohol misuse increased depression symptom-severity 180%**

# Research Questions

- The proposed project is a fully-powered randomized controlled trial of a Web/Smartphone-based + texting alcohol brief intervention (WT-BI) versus an Enhanced Usual Care (EUC) condition for National Guard members in the State of Ohio who meet criteria for at-risk drinking

# Research Questions & Hypotheses

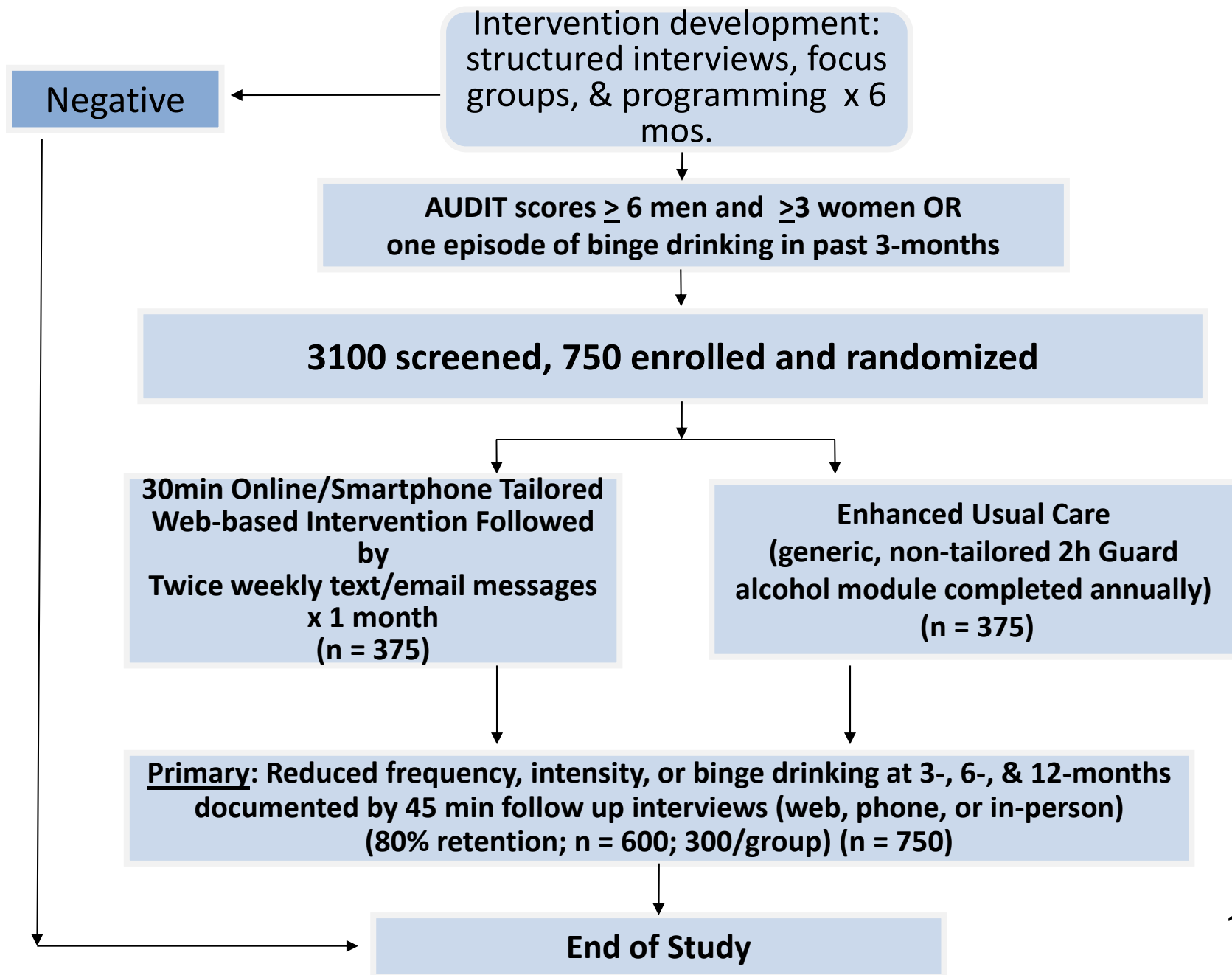
## Alcohol Intervention

- AIM 1:** Compare web/smartphone- and text-based alcohol brief interventions and Enhanced Usual Care.

- H1** – Participants randomized to the web/smartphone- and text-based alcohol brief intervention condition will report significantly fewer days/weeks drinking and fewer drinks/day than participants in the enhance usual care condition at follow-ups

- H2** – Participants randomized to the web/smartphone- and text-based brief alcohol intervention condition will report significantly fewer binge drinking episodes compared to the enhanced usual care participants at follow-ups.

## Alcohol Prevention Study



# Uniqueness of DoD Study

- Given the rapidly changing mobile health field, with dramatic increases in the use of smartphone technologies, we plan to develop and test a mobile phone app for delivery of the intervention content, and for providing real-time feedback and support for drinking goals.
- Three different booster strategies will be examined across the studies (peer, web, phone text), thus providing DoD with data to weigh efficacy and cost in selecting from among these strategies for future implementation.
- Key Differences between NIAAA (Blow) and DoD projects (Calabrese)
  - Intervention Focus (alcohol + prescription drugs vs. alcohol only)
  - Delivery Platforms (web + peer delivered vs. smartphone)
  - Exploration of Mechanisms of Change (moderators/mediators)